November 2001

INTERIM GUIDANCE FOR FOOD AND AGRICULTURE SAFETY AND SECURITY IN CALIFORNIA

CALIFORNIA DEPARTMENT OF HEALTH SERVICES
FOOD AND DRUG BRANCH

BACKGROUND

The potential for contamination of our food supply has always been present. The food industry has responded with sound food production, processing and distribution practices to minimize this threat. Now a rise in terrorism has increased the potential for food contamination[1]. Sound security practices are needed to minimize this threat to public safety and the food industry. The security practices listed below are recommended for all food operations; the attached checklist offers more specific suggestions that may not always be appropriate or even feasible for your food operations. The goal of these security practices is to reduce the likelihood of a terrorist attack on your operations and to reduce a successful attack's impact to you, your business partners and the public. While the terrorist risk to an individual business is low, sound security practices represent good public health and smart business sense.

We recommend that you consider any trusted employees as your advisors in designing and implementing new security practices. The "ownership" of your practices by employees will be your most valuable line of defense.

IDENTIFY SECURITY WEAK SPOTS

Identify the Weak Spots

The initial step is to identify the security weak spots for each activity or step in the process of food preparation. To understand the flow of events in food production, it is helpful to first list the sequence for food preparation.

Identify the Resulting Hazards

Once the security weak spots have been identified consider the risk of each resulting hazard. Risk is the probability and severity of loss or negative impact to the food product from exposure to the hazard.

Put yourself in the role of a dedicated terrorist considering an attack on your operations and then review your entire operation from beginning to end. Ask yourself "What if…" type questions and think "outside the box".

[1] The Center for Counterproliferation Research reported that over 1/3 of the 16 confirmed cases of bioterrorism and 31 confirmed biocrimes committed in the U.S. (prior to 1999) involved food or other agricultural products.

Identify points at which unauthorized persons have easy access to your facilities (e.g. via unlocked gates, doors or trucks) and those of your vendors and shippers.

Identify points at which the employees of your vendors, shippers and other businesses you regularly interact with have unnecessary access to a critical part of your operations.

Identify points at which your employees have unnecessary access to a critical part of your operations.

Identify methods by which any person could introduce, store or move unauthorized materials within your operations.

Identify any record "gaps" in the documentation of your product's production, processing and distribution history.

Identify situations in which a terrorist act at or by a supplier, vendor or shipper could impact your operations (e.g., delivery of contaminated ingredient, contamination of your product during shipping).

Assess the food security awareness and commitment of your employees.

DEVELOP AND IMPLEMENT PRACTICES TO FEASIBLY STRENGTHEN AS MANY WEAK SPOTS AS POSSIBLE

Analyze Risk Control Measures

Examine risk control measures for the possible hazards that could be introduced into the operation. Identify and explore specific options and tools that reduce, or eliminate risk. Prioritize the risks and starting with the highest risk identify as many risk control options as possible. To identify an effective control measure it will reduce or eliminate one of the three risk components (probability, severity, or exposure). Other things to consider include the risk control costs and how various risk control options work together.

Make Control Decisions

There are several important points to keep in mind when making a risk control decision. Involve the employees who would be impacted by the risk control decision to the maximum extent in the selection. They can almost always provide ideas to enhance the various options. In addition, be sure to carefully evaluate the impact on the operation of the risk control action. The objective is to choose the option that has the best overall favorable impact on the operation. Once the best possible set of risk control options has been selected, the individual in charge must accept this decision.

Implement Risk Controls

Part of the process of implementing control measures is to inform personnel in the system of the risk management process results and subsequent decisions. Careful documentation of each step in the risk management process facilitates risk communications.

Some degree of security risk is unavoidable. Your goal is to continuously minimize this risk wherever it is feasible to do so. For example, if it is infeasible to lock a door, it might still be feasible to reduce its attractiveness as an entry point (e.g., better lighting) or to know if unauthorized entry has occurred (e.g., alarm, door seals).

Thoroughly inspect incoming raw materials and other supplies and document the inspections.

Keep accurate inventories of incoming raw materials and outgoing finished products. Retain samples for reference purposes.

If products can be returned to you, have a written policy describing how the products are to be handled including the steps that are to be taken to keep returned product separate from regular stock

Do all you can to assure the clear identification of the raw materials (including water) used to produce your product and of the finished product itself as it moves through distribution channels (ideally the raw materials and finished product would be identified by batch or lot codes). This will help avoid having your safe products being swept off the market with unsafe products and will help agencies trying to determine where, and the means by which, the attack took place.

Use and regularly change passwords (at least eight characters and preferably incorporating some non-alphabetical characters) for computer systems. Make sure anti-virus software is current.

Make sure that employees identified as responsible for security know the roles and responsibilities of the various food safety agencies in California. See Attachment I - Agency List.

Prepare a written recall plan. See Attachment II - FDA Recall Policies.

Prepare a written evacuation and employee safety plan.

Prepare a written plan for continued operation (e.g., at another facility) if your facility becomes temporarily unusable. Identify alternate sources of raw materials and other supplies (including water).

Make and keep current a list of people and agencies (e.g., local fire and police departments, Food and Drug Branch), including alternates, you may need to quickly

contact if an attack occurs involving your facility and the various ways you can contact them (e.g., home and work phones, FAX, E-mail).

Make sure that agencies that may have to respond in an after hours situation (e.g., local Hazardous Materials units) know how to contact you and your employees who are responsible for security. Review facility layout with Hazardous Materials units.

Identify yourself (or select and identify another single employee) to all your employees as being responsible overall for food security issues. Select and identify additional employees to be responsible for parts of your security plan as available and necessary. Be sure to include the selected employees in your security decision-making process and gain their support. These employees should be able at all times during their shifts to know who is, and who should be, at your facility and where. Do not make employees responsible for something they are not able and also authorized to control.

Supervise and Review

Supervision and review process should be systematic and ensure control recommendations have been implemented. In addition, the need for further evaluation of a process due to unanticipated change could result in additional actions. A feedback system is needed to ensure that the corrective or preventive action taken was effective and that any additional corrective action can be implemented as required.

Immediately investigate all reports of suspicious or unusual activity (including missing or excess stock) that might be related to the security of your products or facility. Thoroughly document each investigation in writing. Report any findings of concern to appropriate agencies.

Randomly inspect your facility for compliance with security practices. Hold all employees accountable for understanding and complying with the security practices. Reward employees who report security breaches and weak spots.

Sound security practices will be needed indefinitely. But this does not mean that practices should remain unchanged. Periodically review your practices with the goal of improving security while maintaining or reducing their cost and impact to your facility.

Review the **attached checklist** for suggestions on some specific security practices to consider.

CHECKLIST

Restrict or closely supervise entry by unauthorized persons to your facility or to its critical areas. For example:

Provide nighttime illumination and video surveillance of facility grounds, exterior and interior

Use cardlock type systems and warning signs to restrict critical entry areas to authorized persons

Use metal or metal clad exterior doors

Provide locks, seals, sensors or alarms for doors, windows, skylights and other access points to facility and to areas where raw materials, in-process, finished products, food contact surfaces and packaging are kept. If removable key operated locks are used, remove any codes that could be used to make new keys, uniquely mark the lock (to allow detection if the same type of lock is substituted), individually number keys and closely control their issuance. Minimize the number of keys that need to be carried off-premises, especially if new keys can be made, and limit key access to authorized employees.

Minimize or eliminate vehicle access to water sources and other critical areas. Vehicles can carry large amounts of harmful substances.

Improve the security of your vendors and shippers. For example:

Purchase raw materials and other supplies only from known reputable suppliers and vendors

Ship finished product only with known reputable shippers

Use tamper-evident packaging / seals for your products and their shipping containers

Require the employees of suppliers, vendors and shippers who visit your facility to carry and display photo identification

Require suppliers, vendors and shippers to provide you with written assurances about their own security practices (e.g., background checks, photo identification, sealed containers with seal numbers on shipping documents, lot code traceability, product return handling procedures, recall procedures)

Screen all new employee applicants (including seasonal, temporary and contract). For example (applicant approval for screening should be obtained during the hiring process):

- Obtain references from previous employers
- Conduct criminal background checks
- Perform drug testing

Closely supervise new employees. For example:

- Place new employees on shifts where oversight by senior employees is most likely.

Closely supervise all employees. For example:

- Perform random drug testing (check with an attorney to determine how to obtain approval and implement).
- Limit employee access to those areas of your facility necessary for the employee's position. Use daily shift specific rosters
- Prohibit or restrict personal items (e.g., lunch containers, purses) in facility or in critical facility areas
- Provide management owned locks for employee lockers and establish authority to enter lockers randomly for security checks. (Check with an attorney to determine how to obtain approval and implement).
- Install metal mesh lockers that permit employee locker contents to be visible.
- Issue identification badges with photos and ID numbers. Closely control these badges (e.g., keep unissued badges in a secure location, be sure that persons leaving your employment turn in their badges).

Periodically review your practices. For example

- Regularly train employees about your security practices (especially when the practices change) and test their compliance.
- Hire security patrols or services (e.g., monitoring video surveillance equipment)
- Join one or more industry associations where security ideas and concerns can be shared and discussed.

Attachment I – Agency List

State Agency Contact Information
Food and Agriculture Security

Immediately Report Information on credible threats to:
Local Law Enforcement Officials and Office of Emergency Services Warning Center (916) 262-1621 and/or
Federal Bureau of Investigation Regional Offices at (916) 481-9110 (Sacramento),
(415) 553-7400 (San Francisco), (858) 564-1255 (San Diego), (310) 996-5000 (Los Angeles)

Suspected Food or Water-Borne Human Health Hazard	Suspected Animal Feed Contamination	Suspected Animal Disease or Infestation That May Threaten Animal Agriculture	Suspected Plant Disease or Infestation That May Threaten Agriculture
Contact local Public Health Office (see telephone directory Government pages – Local or County Health Dept.) **Department of Health Services** (DHS) Food and Drug Branch (916) 445-2264 DHS DUTY OFFICER (916) 328-3605* DHS Division of Communicable Disease Control (510) 540-2566 Duty Officer (800) 971-9631*	California Department of Food and Agriculture, Inspection Services Headquarters, Sacramento (916) 654-0574 Modesto Office (209) 491-9347 Fresno Office (559) 452-9687 Ontario Office (909) 930-9689	Producers should contact their veterinarian *first,* then: California Department of Food and Agriculture, Animal Health Branch Headquarters, Sacramento (916) 654-1447 Redding District Office* (530) 225-2140 Modesto District Office* (209) 491-9350 Fresno District Office* (559) 237-1843 Ontario District Office* (909) 947-4462 **California Animal Health and Food Safety Laboratory System** Central Laboratory, Davis (530) 752-8709 Fresno Branch Laboratory (559) 498-7740 San Bernardino Branch Laboratory (909) 383-4287 Tulare Branch Laboratory (559) 688-7543 Turlock Branch Laboratory (209) 634-5837	**Contact County Agriculture Commissioners (see telephone directory Government pages) *first*, then:** **California Department of Food and Agriculture, Plant Health and Pest Prevention Services** Headquarters, Sacramento (916) 654-0317 Fresno District Office (559) 445-5472 San Jose District Office (408) 254-8573 San Diego District Office (619) 698-0211 Bell District Office (323) 881-6961 Van Nuys District Office (818) 901-0719 Riverside District Office (909) 782-4190 Plant Pest Diagnostics Laboratory (916) 262-1100

* 24 hours a day emergency contact

Federal Agency Contact Information
Food and Agriculture Security

Immediately Report Information on credible threats to:
Local Law Enforcement Officials and Office of Emergency Services Warning Center (916) 262-1621 and/or
Federal Bureau of Investigation Regional Offices at (916) 481-9110 (Sacramento),
(415) 553-7400 (San Francisco), (858) 564-1255 (San Diego), (310) 996-5000 (Los Angeles)

Suspected Food or Water Borne Human Health Hazard	**Suspected Animal Disease or Infestation That May Threaten Animal Agriculture**	**Suspected Plant Disease or Infestation in Imported or Exported Products That May Threaten Agriculture**
Call your Local or **County Public Health Office** first. **U. S. Centers for Disease Control and Prevention** (707) 488-7100*	U. S. Department of Agriculture, Animal and Plant Health Inspection Services, Veterinary Services **CA/NV Area Office** **(916) 857-6170 or Toll Free (877) 741-3690***	**U. S. Department of Agriculture – Animal and Plant Health Inspection Service** Headquarters (916) 857-6241 Smuggling Interdiction Teams Bay Area (650) 821-8664 Imperial Co./San Diego (619) 662-7333 Los Angeles (323) 881-6961 Or **call your local Port Director (see telephone directory Government pages under U.S. Customs).** **U.S. Customs** (Imported Products) San Diego (619) 671-8920 San Francisco (415) 782-9375 **U.S. Food and Drug Administration** (Exported Products) Division of Emergency Investigation Operations (301) 443-1240*

- 24 hours a day emergency contact

Federal and State Agency Web site Addresses:

California Department of Health Services www.dhs.ca.gov
California Department of Food and Agriculture www.cdfa.ca.gov
University of California - Animal Health and Food Safety Services Laboratory http://cahfs.ucdavis.edu/
U. S. Department of Agriculture - Animal and Plant Health Inspection Services www.usda.aphis.gov
U.S. Food and Drug Administration www.fda.gov
U. S. Centers for Disease Control and Prevention www.cdc.gov

Attachment II – FDA Recall Policies

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Industry Affairs Staff Brochure
August 2000

FDA Recall Policies

The recall of a defective or possibly harmful consumer product often is highly publicized in newspapers and on news broadcasts. This is especially true when a recall involves foods, drugs, cosmetics, medical devices, and other products regulated by FDA.

Despite this publicity, FDA's role in conducting a recall often is misunderstood not only by consumers, but also by the news media, and occasionally even by the regulated industry. The following headlines, which appeared in two major daily newspapers, are good examples of that misunderstanding: "FDA Orders Peanut Butter Recall," and "FDA Orders 6,500 Cases of Red-Dyed Mints Recalled." The headlines are wrong in indicating that the Agency can "order" a recall. FDA has no authority under the Federal Food, Drug, and Cosmetic Act* to order a recall, although it can request a firm to recall a product.

Most recalls of products regulated by FDA are carried out voluntarily by the manufacturers or distributors of the product. In some instances, a company discovers that one of its products is defective and recalls it entirely on its own. In others, FDA informs a company of findings that one of its products is defective and suggests or requests a recall. Usually, the company will comply; if it does not, then FDA can seek a court order authorizing the Federal Government to seize the product.

This cooperation between FDA and its regulated industries has proven over the years to be the quickest and most reliable method to remove potentially dangerous products from the market. This method has been successful because it is in the interest of FDA, as well as industry, to get unsafe and defective products out of consumer hands as soon as possible.

FDA has guidelines for companies to follow in recalling defective products that fall under the Agency's jurisdiction. These guidelines make clear that FDA expects these firms to take full responsibility for product recalls, including follow-up checks to assure that recalls are successful.

Under the guidelines, companies are expected to notify FDA when recalls are started, to make progress reports to FDA on recalls, and to undertake recalls when asked to do so by the Agency.

The guidelines also call on manufacturers and distributors to develop contingency plans for product recalls that can be put into effect if and when needed. FDA's role under the guidelines is to monitor company recalls and assess the adequacy of a firm's action. After a recall is completed, FDA makes sure that the product is destroyed or suitably reconditioned and investigates why the product was defective.

The guidelines categorize all recalls into one of three classes according to the level of hazard involved.

Class I recalls are for dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are a food found to contain botulinal toxin, a label mix-up on a lifesaving drug, or a defective artificial heart valve.

Class II recalls are for products that might cause a temporary health problem, or pose only a slight threat of a serious nature. One example is a drug that is understrength but that is not used to treat life-threatening situations.

Class III recalls are for products that are unlikely to cause any adverse health reaction, but that violate FDA regulations. An example might be bottles of aspirin that contains 90 tablets instead of the 100 stated on the label.

FDA develops a strategy for each individual recall that sets forth how extensively it will check on a company's performance in recalling the product in question. For a Class I recall, for example, FDA would check to make sure that each defective product has been recalled or reconditioned. In contrast, for a Class III recall the Agency may decide that it only needs to spot check to make sure the product is off the market.

Even though the firm recalling the product may issue a press release, FDA seeks publicity about a recall only when it believes the public needs to be alerted about a serious hazard. For example, if a canned food product, purchased by a consumer at a retail store, is found by FDA to contain botulinal toxin, an effort would be made to retrieve all the cans in circulation, including those in the hands of consumers. As part of this effort the Agency also could issue a public warning via the news media to alert as many consumers as possible to the potential hazard.

FDA also issues general information about all new recalls it is monitoring through a weekly publication titled "FDA Enforcement Report" which is available by subscription from the Superintendent of Documents, Government Printing Office. For price and ordering information, contact the Government Printing Office, Washington, DC 20402, Telephone 202-512-1800; or fax to 202-512-2233. The latest issues of the FDA Enforcement Report are available on FDA's Internet Website www.fda.gov/opacom/enforce.html

For additional information on recalls, contact the FDA District Office nearest you.

* Sec. 412 and Sec. 518 Food Drug and Cosmetic Act.; Sec. 351 Public Health Service Act.